
AEGIS Anterior Lumbar Plate System

IX. 510(k) Summary

FEB 3 2006

SUBMITTER: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02780

CONTACT PERSON: Mary Gray
Phone: (508) 828-3649
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DATE PREPARED: January 12, 2006

CLASSIFICATION NAME: Spinal Intervertebral Body Fixation Orthosis
§888.3060

PROPRIETARY NAME: AEGIS Anterior Lumbar Plate System

PREDICATE DEVICES: DePuy AcroMed M-2 Anterior Plate System, K972718
Medtronic Sofamor Danek PYRAMID Anterior Plate
Fixation System, K013665

DEVICE DESCRIPTION: The AEGIS Anterior Lumbar Plate System consists of
an assortment of plates and screws.

The AEGIS Anterior Lumbar Plate System also
contains Class 1 manual surgical instruments and
cases that are considered exempt from premarket
notification.

INTENDED USE: The indications for use for the devices described in
this submission are as follows:

The AEGIS Anterior Lumbar Plate System is indicated
for use as an anteriorly placed supplemental fixation
device via the lateral or anterolateral surgical
approach above the bifurcation of the great vessel or
via the anterior surgical approach, below the
bifurcation of the great vessels.

AEGIS Anterior Lumbar Plate System

The device is intended as a temporary fixation device until fusion is achieved. The AEGIS Anterior Lumbar Plate System is intended for anterior lumbar (L1 - S1) fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

MATERIALS:

Manufactured from ASTM F-136 implant grade titanium alloy.

PERFORMANCE DATA:

Performance data were submitted to characterize the AEGIS Anterior Lumbar Plate System components.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Ms. Mary Gray
Senior Regulatory Affairs Associate
Depuy Spine
325 Paramount Drive
Raynham, MA 02767

Re: K052546

Trade Name: AEGIS Anterior Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation System
Regulatory Class: II
Product Code: KWQ
Dated: January 12, 2006
Received: January 13, 2006

Dear Ms. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a stylized, flowing script.

 Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052546

Device Name: AEGIS Anterior Lumbar Plate System

Indications For Use:

The AEGIS Anterior Lumbar Plate System is indicated for use as an anteriorly placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels.

The device is intended as a temporary fixation device until fusion is achieved. The AEGIS Anterior Lumbar Plate System is intended for anterior lumbar (L1 - S1) fixation for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052546

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